REMARKS

This is in further response to the Office Action mailed December 24, 2003 and the Advisory Action mailed May 10, 2004.

In that Office Action, Claims 1, 3-5, 7-10, and 5-28, were rejected under 35 USC §102, as being anticipated by U.S. Patent No. 6,544,727 to Hei ("Hei").

Claims 25-28 were rejected under 35 USC §112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention.

Also, the specification was objected to because it was deemed to include new matter. Specifically, it was deemed that the material added by the previous Amendment to the specification (regarding the concentration of acetate), was new matter.

An Amendment to the final Office Action was submitted on April 24, 2004. As set forth in the Advisory Action, that Amendment was not entered on the grounds that it raised new issues requiring further consideration. Accordingly, Applicants submit the present Amendment together with a Request for Continued Examination.

Claim 1 has been amended to recite a method for preparing a pathogen inactivation treatment-ready blood product that includes the steps of providing a container system having a pre-

connected interim container and a container including a liquid synthetic medium. The medium container is in openable flow communication with the interim container. The method further includes providing a source container that includes a quantity of a blood component separate from the container system and establishing fluid communication between the source and interim containers. The method of Claim 1 further includes transferring the blood component to the interim container, and centrifuging the interim container to substantially separate the transferred blood component into a layer of the blood component and a supernatant component layer. The method also includes substantially removing the supernatant layer from the interim container and combining a selected quantity of the blood component with a selected quantity of the synthetic medium within the interim container to provide a blood product with a pre-selected ratio of the blood component to said synthetic medium in a way that is effective for pathogen inactivation treatment.

Applicants respectfully submit that the above-recited steps are not expressly shown nor fairly supported in the Hei patent. In particular, the systems shown in Figures 49 and 50, and the corresponding discussion regarding the same, are directed to an apheresis system, which can be (pre)programmed to add a selected amount of a storage solution during or immediately after the

collection of the desired component. In each example, however, the storage medium is part of the apheresis kit and does not include the further centrifugation of the container holding the collected and desired component. Thus, Hei does not appear to disclose the step of centrifuging a container that includes the collected blood component as recited in Claim 1, as amended. Accordingly, Applicants submit that Claim 1 is not anticipated by the Hei patent.

In contrast to the systems and methods described relative to Figures 49 and 50, or Example 42, of the Hei patent, it will be appreciated that the method of the present invention is intended to be used where the apheresis or collection system is not (pre)programmed for addition of a pre-selected amount of storage solution and plasma to achieve a pathogen inactivation-ready product. As described in paragraphs [00013] and [00014] of the present application, certain existing apheresis systems do not provide a blood component product that is ready for pathogen inactivation in certain established pathogen inactivation protocols. It is for this reason, that the method of the present invention was developed, namely, to allow for the conversion of these blood component products, collected by different apheresis systems, to such pathogen inactivation-ready products. Thus, the present invention addresses a current need in the field of pathogen inactivation. For these reasons,

Applicants submit that the claims of the present application are not anticipated by, nor would they have been obvious in view of U.S. Patent No. 6,544,727 to Hei.

With respect to the rejections under 35 USC §112, Claim 25 has been amended to overcome the rejection. Claims 26 and 27 have been cancelled, and Claim 28 has been made dependent on amended Claim 25.

Finally, with respect to the objection to the specification, Applicants submit that the amendment made in the previous Response merely corrected a typographical error in the specification. The intended meaning of the corrected passage can be easily deduced from an examination of the remainder of the specification, and for that reason should not be considered new matter. Shimadzu et al. v. Electric Storage Battery Company, 35 F 745, 750, 47 USPQ 12, 17 (E.D. Penn., 1945).

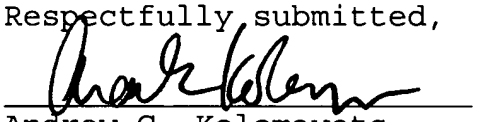
As explained in the previous response, the range "22-5" was actually intended to read "22-35." Applicants submit that this is an obvious error, and that the correct meaning can be deduced from common usage and the neighboring paragraphs of the specification. First, according to standard convention, when reciting ranges, the lower number of said range is always reported first. This makes clear that the concentration of acetate in this preferred embodiment was intended to be either 25 or 35, within the broader preferred embodiment and range of

20-40 mM recited in the previous paragraph. That said, it is further submitted that the upper end of the recited range of acetate can be deduced from the same paragraph and subsequent table, which recites the most preferred concentration of 32.5. Thus, paragraphs [00042] and [00043], when read in context, disclose preferred, more preferred and most preferred compositions of a storage medium that includes the same components. For these reasons, Applicants submit that this obvious typographical error should be correctable in that its intended meaning can be clearly deduced and, in any event, does not expand the scope of the present application.

By this Amendment, Claims 11-24, previously withdrawn from consideration, have also been canceled. Applicants reserve the right to pursue these claims in other continuing applications or make them dependent on allowed claims of this application.

Applicants submit that the claims are now in condition for allowance or, at the very least, in better form for Appeal. Favorable reconsideration of the claims is respectfully requested.

Respectfully submitted,



Andrew G. Kolomayets
Registration No. 33,723

COOK, ALEX, MCFARRON, MANZO,
CUMMINGS & MEHLER, LTD.
200 West Adams Street - #2850
Chicago, IL 60606
(312) 236-8500